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**EP 0 424 494 B1**

## Description

The present invention relates to the controlled delivery of fluids and, in particular, to a system and apparatus for the delivery of a preselected quantity of a beneficial agent to a patient.

The controlled delivery of a preselected quantity of a beneficial agent to a patient is highly desirable in a number of situations. Particularly, the controlled delivery of drugs such as analgesics is highly desirable as there is great difficulty in properly administering analgesics. The need to administer analgesics varies greatly from patient to patient. Such factors as, for example, age, pain tolerance, renal function, and presence of other medications can all affect the pharmacokinetics of such analgesic.

In the area of analgesic administration, there has been much activity in the last several years directed towards letting the patient control how much drug he or she administers. It has been found that, as a group, patients controlling the quantity they receive use less analgesic than patients who must request the administration of a pain killer. One apparent factor is the psychological relief present when a patient knows he or she is in control of the amount of drug to be administered. The amount of drug the patient can self-administer must also be subject to a maximum level of drug.

The efficient patient controlled administration of drug has resulted in several devices on the market. Such devices generally suffer from several drawbacks. Initially, such devices are electromechanical in nature thus requiring an electrical power source. In addition, such devices are large and bulky which limits the patient's freedom to move.

Another drawback of such devices is that they only provide an on-demand rush of the drug as administered by the patient with no constant drug flow to the patient. While this type of drug administration is appropriate for many situations, it is often desirable to have a constant flow of drug to the patient, referred to herein as a continuous flow, supplemented by a patient controlled supplement of drug, referred to herein as a bolus flow. While several devices on the market are designed to provide such continuous flow supplemented by a patient controlled flow, such devices are again electro-mechanical in nature and are large and bulky thus limiting the patients' ability to move. WO-87/00758 discloses an apparatus for administering a bolus flow of a fluid in a manually-controllable way.

While, of course, two separate devices can be utilized to provide this continuous-bolus flow arrangement, such use of two devices adds to the cost and complexity of the system while further limiting patient mobility. What is thus needed is an

apparatus and system for both a constant delivery of a beneficial agent and a patient controlled supplement of the beneficial agent which is low in cost, highly mobile, and easy to use. The present device meets these requirements. The pre-characterising features of claim 1 are based on WO-87/00758, and the distinguishing features of the present invention are set out in the characterising part of claim 1.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a perspective view of a preferred embodiment of a device made in accord with the principles of the present invention;

FIGURE 2 is a cross-sectional view of the means for providing a source of fluid under pressure of the device of FIGURE 1;

FIGURE 3 is a cross-sectional view of a preferred embodiment of the flow regulator means of the device of FIGURE 1;

FIGURE 4 is a cross-sectional view of an alternative preferred embodiment of the flow regulator means;

FIGURE 5 is an enlarged overview of a preferred embodiment of the flow rate wafer of FIGURE 4;

FIGURE 6 is an enlarged overview of an alternative preferred embodiment of the flow rate wafer;

FIGURE 7 is an exploded perspective view of the selector housing for the flow rate wafer of FIGURE 6;

FIGURE 8 is an exploded, partially cut-away perspective view of a preferred embodiment of the bolus means of FIGURE 1;

FIGURE 9 is a cross-sectional view of an alternative preferred embodiment of the bolus means; and

FIGURE 10 is an enlarged overview of an alternative preferred embodiment of a flow rate wafer.

## DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Referring first to Figure 1, a completed assembly in accord with the present invention is designated generally by the reference numeral 10. The completed device generally includes means 12 for providing a source of fluid under pressure, bolus dose means 14 for providing a controlled bolus dose of the fluid, and means 16 for regulating a constant flow rate of fluid. Each means is in fluid communication by means such as flexible tubing 18 made of medical grade plastic such as, for example, polyvinyl chloride. Each tub segment connecting the various means acts as both a down-

stream conduit and an upstream conduit for the two means being connected. For example, the tubing segments 18 between the means for providing a source of fluid 12 and the controlled bolus dose means 14 acts as a downstream conduit for the fluid source means 12 as well as an upstream conduit for the bolus dose means 14.

Referring now to Figure 2, a preferred embodiment of the means for providing a source of fluid under pressure 12 is seen. The presently preferred means is a device such as the Infusor sold by Baxter Healthcare Corporation (formerly Travenol Laboratories) of Deerfield, Illinois and shown in U.S. Patent No. 4,741,733 to Winchell et al, which is assigned to the assignee of the present invention and which disclosure is incorporated herein.

Such device includes a tubular housing 22. An elastomeric bladder 24 which is contained in the tubular housing 22 contains the fluid or beneficial agent 26 which is to be delivered.

The elastomeric bladder 24 of the assembly is self pressurized; that is, as a liquid such as the beneficial agent 26 is injected through means for receiving liquid under pressure, the elastomeric bladder 24 expands. The elastomeric bladder 24 exerts a substantially constant pressure on the fluid 26 throughout the volume range of the elastomeric bladder 24. The pressure within bladder 24 on the fluid 26 therein can preferably be about 55 KPa (8 P.s.i.)

The bladder 24 is secured at a free end 34 to a floating piston 30. The floating piston 30 includes the means for receiving a liquid under pressure 28 so that the expandable bladder 24 can be filled. Such means can include a one-way valve contained in the housing having threaded receiving means for receiving a syringe absent a hypodermic needle for providing the fluid under pressure. Such means can alternately include a rubber membrane through which a syringe having a hypodermic needle can pierce to provide the fluid under pressure.

The bladder 24 is secured at a fixed end 36 to a plug 32 which is mounted to the housing 22. The plug 32 may be unitary with the housing 22. The free end 34 and fixed end 36 may be secured to the floating piston 30 and plug 32, respectively, by means of wire clamps 38, banding or the like. As fluid 26 is expressed from the expanded bladder 24, the floating piston 30 moves toward the plug 32. The plug 32 includes an aperture 40 extending therethrough which is in fluid communication with the inside of bladder 24.

A filter element 42 such as a polyester screen filter can be mounted across the aperture 40 to filter fluid 26 flowing out of bladder 24. The plug 32 may include an end piece 44 secured to the plug 32 by, for example, sonic welding to mount the filter element 42 within plug 32 and to secure the

first segment tubing 18 to plug 32.

The tubing 18 includes a proximal end 46 and a distal end 47. The tubing proximal end 46 is secured to the end piece 44 of plug 32 by, for example, adhesive or the like. The distal end 47 is secured to a Y-connector 48, as will be explained in more detail below.

Referring now back to Figure 1, the means 16 for regulating a constant flow rate of the fluid and the bolus dose means for providing a controlled bolus dose of the fluid 14 are seen. The means for regulating a constant flow rate of the fluid 16 is in fluid communications with the means for providing a source of fluid under pressure 12 via the tubing 19.

Referring now to Figure 3, a preferred embodiment of the flow regulator means 16 is seen. Such flow regulator means is also shown in U.S. Patent No. 4,741,733 to Winchell et al. The flow regulator means 16 includes regulator housing 52 having a flow regulator 64 dispensed therein. The regulator housing 52 is secured at an inlet passage 54 to tubing 18 extending from the Y-connector 48 by, for example, solvent bonding about the outside diameter of tubing 18.

Opposite the inlet passage 54, the regulator housing 52 includes an enlarged outlet passage 56 forming an annular flange with and being connected to an internally threaded sleeve 58 of a locking Luer 60. The Luer lock 60 includes a Luer taper element 62 which is adapted for connection with a female Luer contained on a downstream tube segment.

A sealing element such as an O-ring 63 is disposed around the periphery of flow regulator 64 to prevent fluid from flowing between the outside of regulator 64 and regulator housing 52. The O-ring 63 is mounted in an annular channel around the periphery of flow regulator 64. The channel has a triangular cross section. The three sides of the channel are formed by the flow regulator 64, a beveled corner of the enlarged end of housing 52 and the threaded sleeve 58 of the connecting means.

The O-ring 63 is pressed within and conforms to the shape of the channel as the channel is formed. The channel is formed when the threaded sleeve 56 and the enlarged end of housing 52 are secured together by means such as, for example, sonic welding. The pressure placed on the sealing element 63 by the threaded sleeve 58 and the enlarged end of housing 52 deforms the O-ring 63 substantially into the shape of the channel thereby effectively sealing the flow regulator 64 and the housing 52. Thus, different length flow regulators 64 can be utilized in the housing 52.

In a preferred embodiment, the flow regulator 64 includes a capillary-type flow restrictor. On

such capillary-type flow restrictor can be made of glass which defines a very small bore in fluid communication with the tubing.

The fluid flow rate through the tubing 18 is determined by the characteristics of the capillary-type flow restrictor along with the characteristics of the fluid which flows through the flow restrictor. In a glass bore flow restrictor, the flow rate can be changed by varying the cross-sectional area and length of the regulator bore.

In a second preferred embodiment, the flow regulator includes a flow restrictor chip or wafer encapsulated in housing. Such a device is shown in U.S. Application Serial No. 167,822 to Winchell et al. which is assigned to the assignee of the present invention which disclosure is incorporated herein. Referring to Figure 4, this alternative preferred embodiment is seen in detail.

The flow restrictor chip 70 is contained in housing 72 which includes a locking Luer 74 contained at the end of tubing. The Luer lock 74 includes a Luer taper element 76 adapted for connection with a female Luer contained on downstream tubing.

A seal member 77 is located between an inlet passage 78 and an outlet passage 80. The wafer or chip 70 is carried within seal member 77 with the wafer 70 having an inlet in fluid communication with the inlet passage 78 and the wafer 70 having an outlet in fluid communication with the outlet passage 80. All fluid traversing the housing 72 must pass through the flow restrictor path of wafer or chip 70. The wafer or chip 70 thus serves to regulate the flow rate of the fluid.

Referring now to Figure 5, a preferred embodiment of the wafer or chip 70 is seen in detail. The wafer 70 includes a base substrate 82 into which one or more flow restrictor paths 84 are formed. These paths can be of various geometrics such as V-shaped, arcuately shaped or rectangularly shaped, depending on the nature of the substrate and the etching technique utilized. In the illustrated embodiment, a single main flow restrictor path 84 is formed having a preselected discrete resistance to fluid flow.

The path may be enclosed by various means such as an overlay (not seen) covering the base substrate 82 to enclose the restrictor path 84. The inlet 86 and outlet 88 of wafer 70 are formed as apertures in base substrate 82 which form fluid communication paths at opposite ends of flow restrictor path 84.

Manifold regions 90 can also preferably be preformed on the base substrate 82 at opposite ends of flow restrictor path 84 to assure a non-restricted flow on the wafer 70. Also, a plurality of secondary flow restrictor paths 92, with each secondary flow restrictor path 92 smaller than the main

flow restrictor path 84, can be provided to filter out small particulate matter during passage across the wafer 70.

In an alternative embodiment of the presently preferred flow control means 14, a wafer or chip 70 having at least two independent flow restrictor paths formed on the base substrate can be utilized. Such a wafer is seen in Figure 6 in which four flow restrictor paths are seen.

In this embodiment, the four restrictor paths 100, 102, 104, 106 are formed between a central wafer inlet 108 and first 110, second 112, third 114 and fourth 116 restrictor outlets. Each path is formed with a preselected cross sectional area and length to provide a different resistance to flow. Fluid transversing each flow restrictor path will therefore flow at a different, preselected flow rate.

The wafer again includes fluid manifolds 90 formed in association with each flow restrictor path 100, 102, 104, 106. In addition, filtration areas 92 can also once again be formed.

The multi-path flow restrictor chip is contained in selector housing 120. Referring to Figure 7, the selector housing 120 is seen in detail. The selector housing 120 includes a base member 122 and a selector member 124 which is normally carried on the base member 122. The base member 122 includes a well 126. An inlet passage 128 communicates with the well 126 by means of an inlet port 130. An outlet passage 132 also communicates with the well 126 by means of an outlet port 134. The inlet 128 and outlet 132 passages are in fluid communication with tubing 18.

The inlet port 130 is located generally along the centerline of well 126. The outlet port 134 is radially spaced a selected distance from the inlet port 130. An elastomeric seal member 138 occupies the well 126. The seal member 138 includes first 140 and second 142 apertures which extend through the body of seal member 138. When the seal member 138 is properly positioned in well 126, the first aperture 140 registers with the inlet port 130 and the second aperture 142 registers with the outlet port 134. A pair of locating pins 146 are positioned in well 126 which mate with a pair of locating holes 148 in seal member 138 to align and retain the seal member 138 in the desired position in well 126.

The selector member 124 is rotatable on the base member 122 about an axis generally aligned with the centerline of well 126. The selector member 124 can be rotatably attached to the base member 122 by various means, such as by rotatably affixing by snap-fit engagement between a circumferential flange 120 on the selector member 124 and a mating circumferential ridge 152 on the base member 122.

The flow restrictor wafer 70 is carried by the selector member 124. More particularly, projecting ridges 154 formed within the inner wall of selector member 124 define a space generally corresponding to the shape of wafer 70. The wafer 70 is carried within this space with the ridges 154 contacting the peripheral edges of wafer 70 and preventing lateral movement of wafer 70.

As such, the wafer inlet 108 is in alignment with the inlet port 130 of base member 122 via the first aperture 140 in seal member 138. As the wafer 70 is carried for movement in common with the selector member 124, the inlet 108 of wafer 70 stays in alignment with the inlet port 130. This rotation also serves to place the various outlets 110, 112, 114, 116 of wafer 70 into and out of alignment with the outlet port 134 of base member 122 via the second aperture 142 in seal member 138, depending on the position of the selector member 124 within its circular path. As such, different flow rates can be selected in this embodiment by simply rotating the selector member 124.

Referring now back to Figure 1, the means 14 for providing a controlled bolus dose of the fluid is seen. Such controlled bolus dose means is shown in U.S. Application Serial No. 308,972 to Winchell et al. which is assigned to the assignee of the present invention and which disclosure is incorporated herein.

The preferred embodiment of the controlled bolus dose means 14 includes a bolus dose apparatus 15 which includes housing 160 which can be worn in the same manner as a wristwatch. The housing 160 can include wristband portions 162 secured to the housing 160 by mounting pins 164 to which the wristband portions 162 are secured.

Referring now to Figures 8 and 9, the housing 160 of bolus dose apparatus 15 is seen in detail. The housing 160 includes a back plate 166 secured by securing means such as screws 168 to a casing 170. Alternatively, the back plate 166 can be permanently secured by means such as sonic welding. A portion of back plate 166 can include a raised plateau 172 that forms one wall of a dose reservoir 174. A dose reservoir inlet 176 and a dose reservoir outlet 178 are formed within back plate 166. The inlet 176 includes a channel portion 180 and a bore portion 182 in fluid communication with the channel portion 180 and the interior of dose reservoir 174. The upstream tubing 18 is secured into the bore portion 180 by means such as friction fit or solvent bonding. The channel portion serves as a track to trap the conduit in a fixed location when the back plate 166 is secured to the casing 170.

The dose reservoir outlet 178 includes an outlet channel portion 182 and an outlet bore portion 184 in fluid communication with the interior of dose

reservoir 174 and outlet channel portion 182. The downstream tubing 18 is secured to the outlet bore 182 by means such as a friction fit or solvent bonding.

The dose reservoir 174 includes an enclosed flexible container which can be compressed to force expulsion of the contents of dose reservoir 174. In one embodiment, this dose reservoir 174 can be a circular flexible sheet 188 placed on top of raised plateau 172 of back plate 166. The periphery of circular flexible sheet 188 rests on the periphery of raised plateau 172. The circular flexible sheet 188 may be made of, for example, polyisoprene rubber material.

The dose reservoir 174 can be formed by utilizing a pressure seal structure in the housing to press the flexible sheet 188 adjacent to its outer periphery against the raised plateau 172 creating a fluid tight seal between the flexible sheet 188 and the plateau 172. More particularly, the casing 170 can include a downwardly extending annular rib 190 disposed below and outwardly of a guide bore 192 so that the annular rib 190 is directly above the periphery of flexible sheet 188 and raised plateau 172. When the back plate 166 is secured to the casing 170 such as with the screws or sonic welding, the periphery of flexible sheet 188 is trapped between the annular rib 190 and the raised plateau 172.

In an alternative embodiment, seen in Figure 9, the dose reservoir 174 can include two flexible sheets 196 sealed together about the outer periphery of each to define a pillow 198. This pillow 198 is the enclosed flexible container contained in casing 170. The two flexible sheets 196 can be made of, for example, vinyl. The outer periphery seal includes apertures through which the upstream and downstream tubing extends to establish fluid communication with the inside of pillow 198. In this alternative embodiment, the back plate 166 need not include a raised plateau.

The control means of the apparatus includes dose reservoir compression means which in a preferred embodiment includes a floating plate 200 that rests on top of flexible sheet 188 or pillow 198 and has a diameter less than the diameter of guide bore 192. The floating plate 200 can include an upped annular ridge 202 projecting from the top side of floating plate 200 at its periphery. The floating plate 200 can further include two volume indicator pegs 204 projecting from the upper annular ridge 202.

A casing ridge 206 projects inwardly from the guide bore 192 at the top of guide bore 192 and acts as a stop that is part of the dose compression means. The floating plate 200 travels in a direction perpendicular to the back plate 166, the stop serving as an upper limit for the floating plate 200 when

the upper annular ridge 202 thereof engages the stop.

The casing 170 defines an opening 210 for the control switch 212. Part of opening 210 is directly above the guide bore 192 and the floating plate 200. The defined opening 210 of casing 170 includes slots 214 in which the volume indicator pegs 204 of floating plate 200 travel as the floating plate 200 reaches its upper limit.

The control switch 212 is rotatably mounted upon a cylindrical pin 216 mounted in receiving sockets 218 within casing 170. The control switch 212 includes two mounting flanges 220 each having a pin opening 222 through which the pin 216 extends.

The control switch 212 rotates within a narrow arc about the axis of pin 216. A coil-type spring 224 is also mounted about the pin 216 between the mounting flanges 220. The pin 216 extends through the inside of coil-type spring 224. The spring 224 includes contact ends 226, 228. A spacer 230 is mounted on the pin 216 between the coil-type spring 224 and the pin 216. The contact ends 226, 228 tend to move circumferentially relative to the axis of pin 216 and the axis of coil-type spring 224.

The contact end 226 contacts and urges against the underside of control switch 212. The second contact end 228 contacts and urges against a shelf 232 in casing 170. The coil-type spring 224 thus serves as biasing means of the apparatus.

The control switch 212 can also include a blunt end conduit occlusion bar 236 made integrally with the control switch 212 and forming a single rigid part. The conduit occlusion bar 236 depends downwardly from the valve end 238 of control switch 212. The conduit occlusion bar 236 acts with the flexible wall portion 240 of downstream tubing 18 to form valve means for the apparatus.

Referring now to Figure 10, another alternative preferred embodiment of the flow rate wafer is seen. This alternative embodiment is referred to herein as a dual wafer 250. This embodiment includes a wafer inlet 252, a continuous flow outlet 254, and a bolus flow outlet 256. The wafer 250 can include a fluid manifold 90 formed in association with the wafer inlet 252. In addition, a filtration area 92 can also be provided in association with the wafer inlet 252.

The wafer inlet 252, fluid manifold 90, and filtration area 92 are in fluid communication with both a continuous restrictor path 260 and a bolus restrictor path 262. The restrictor paths 260, 262 are formed with a preselected cross-sectional area and length to provide different restriction to flow. Fluid transversing the two flow paths 260, 262 will therefore flow at different preselected flow rates. The continuous restrictor path 260 is in fluid communication with the continuous flow outlet 254

while the bolus restrictor path 262 is in fluid communication with the bolus flow outlet 256.

Referring back to Figure 8, housing 270 for the dual wafer 250 of Figure 10 is seen in conjunction with the housing 160 of bolus dose apparatus 15. The housing 270 includes two inlet ports 272, 274 and two outlet ports 276, 278. The first housing inlet port 272 is in fluid communication with the means for providing a source of fluid under pressure 12 by means of tubing 18. The first housing inlet port 272 is thus connected to tubing 18 by means such as an adhesive. The first housing inlet port 272 is in fluid communication with the dual wafer inlet 252. As such, fluid enters the housing 270 through the first housing inlet port 272 and then flows through the dual wafer inlet 252 to the fluid manifold 90 of dual wafer 250. After flowing through the filtration area 92, the fluid flows in parallel through the continuous restrictor path 260 and the bolus restrictor path 262.

The first housing outlet 276 is in fluid communication with the bolus flow outlet 256 of dual wafer 250. The first housing outlet 276 is also in fluid communication with the input of bolus dose apparatus 15 by means such as tubing 18. The second housing input 274 is in fluid communication with the outlet of bolus dose apparatus 15. The second housing outlet 278 is in fluid communication with both the continuous flow outlet 254 of dual wafer 250 and the second housing input 274. The second housing outlet 278 is also in fluid communication with downstream tubing 18. The continuous fluid flow passes through the continuous restrictor path 260 to the second housing outlet 278. The bolus fluid flow passes through the bolus restrictor path 262 to the bolus dose apparatus 15, then from the bolus dose apparatus 15 to the housing second input 274, and then to the housing second outlet 278.

Referring again to Figure 1, the operation of the device will be described. As previously seen, the means for providing a source of fluid under pressure 12 can preferably provide the fluid or beneficial agent at a pressure of about 55 KPa (eight PSI). In one embodiment, this beneficial agent under the flow rate pressure is split into two flow paths by a Y-connector 48. The two flow paths are a continuous flow path 290 and a bolus flow path 292. The continuous flow path 290 leads to a constant flow regulator means 16. The bolus flow path 292 leads to a bolus flow regulator means 300 which in the preferred embodiment can include the same type flow restrictor as the constant flow regulator means 16, be it the glass capillary type, the wafer type, or the multi-channel adjustable wafer type.

In the alternative embodiment, the means for providing a source of fluid under pressure 12 is

provided to the inlet 252 of dual wafer 250. The continuous flow path 290 is thus formed by the continuous restrictor path 260 while the bolus flow path 292 is formed by the bolus restrictor path 262.

The means for providing a source of fluid under pressure 12 and tubing 18 up to the two flow regulators define an approximate closed pressure system. This is because the flow rate through the flow restrictors is sufficiently small to maintain the closed pressure system at about 55 KPa (eight PSI). As such, the fluid pressure at the inlet of the fluid flow restrictors of the present device remains at about 55 KPa (eight PSI). It has been found that by keeping a closed pressure system and utilizing two flow restrictors in such parallel arrangement, no lag time is experienced. Lag time is that amount of time needed in series flow restrictors to replenish the pressure upstream of the constant flow restrictor after a bolus dose is administered.

In the continuous flow path 290, the flow rate pressure is supplied to the constant flow regulator means 16. The beneficial agent then flows through the constant flow regulator means 16 which governs the rate of flow of the fluid. In a preferred example, the continuous flow rate is set at about 0.5 ml per hour of the beneficial agent as determined by the length and diameter of the capillary bore.

From the outlet passage of the constant flow regulator means 16, in the first embodiment, tubing 18 is connected in direct fluid communication with a downstream Luer 308 by means such as, for example, a second Y-connector 306. In the alternative embodiment, the second housing outlet 278 of dual wafer housing 270 is directly connected to the downstream Luer 308 as a Y-type configuration is built into the housing 270. The downstream Luer 308 is adapted to be connected to a catheter for introduction into a patient's vein.

The bolus flow path 292 is also supplied to the bolus dose means 14 by an inlet passage of a bolus flow regulator means 300. In this second flow regulator means, the flow regulator sets the rate at which the bolus means dose reservoir 174 fills with fluid. In a preferred example, the bolus flow regulator means 300 is set at about 2.0 ml per hour. This rate plus the continuous flow rate represents the total discrete dose amount volume limit above which the patient will not be able to receive the beneficial agent. In the preferred example, the total discrete amount is about 2.5 ml per hour.

The outlet passage of bolus flow regulator means 300 is connected to the inlet passage of bolus dose apparatus 15 by means such as tubing 18. Thus, the bolus flow regulator means 300 and the bolus dose apparatus 15 form the means for providing a controlled bolus dose of the fluid 14. The bolus flow rate fills the dose reservoir 174 to

its maximum volume as defined and limited by the floating plate and the stop, which in a preferred example is approximately 0.5 ml. This maximum volume represents the bolus dose discrete dose limit. The bolus flow rate expands the dose reservoir 174 over time in a linear manner to the maximum volume. As such, if the bolus dose is administered prior to the filling of dose reservoir 174, the amount of bolus dose administered is a linear function of the amount of time which has passed since the last bolus dose up to the time when the dose reservoir 174 is filled to its maximum volume thus attaining the bolus dose discrete dose limit.

The spring 224 biases the valve end of control switch 212, including the conduit occlusion bar 236, downwardly. The spring 224 also biases the end opposite the valve end of control switch 212 upwardly so that the control switch 212, although remaining within the defined opening of casing 270, is spaced from the floating plate 200. The flexible wall portion 240 of the downstream apparatus conduit is disposed directly underneath the conduit occlusion bar 236.

To activate the controlled bolus means dose, the patient pushes the upwardly biased end of control switch 212. This causes the control switch 212 end to contact the floating plate 200 and depress it downwardly out of engagement with the stop and compress the dose reservoir 174 by urging the flexible sheet 188 against the raised plateau 172 or the pillow 198 against the back plate 166. Before contact between the upwardly biased end of control switch 212 and floating plate 200 is made, the biasing force provided by the spring 126 is overcome by the force of the control switch 212 activation, lifting the valve end and the conduit occlusion bar 236 out of engagement with the flexible wall portion 240 of the downstream conduit thus placing the valve means in an open, operating mode.

As the floating plate 200 is urged downwardly by the control means, the dose of beneficial agent within dose reservoir 174 is expressed out of the dose reservoir 174, through the outlet. In one embodiment, the outlet is connected to downstream tubing which is connected to the second Y-connector 306 to establish direct fluid communication with the downstream Luer 308 and catheter. In a second embodiment, the outlet is connected to the dual wafer second housing input 274 which acts as the Y-connector and is in fluid communication with to the downstream Luer 308.

After the control switch 212 has been released by the patient, the flexible wall portion 240 of the downstream apparatus conduit is once again occluded by the blunt-ended conduit occlusion bar 236, thus placing the valve means in the closed mode of operation. In addition, the biasing spring



224 has returned the button end of the control switch to its inactivated, upper position. In this state, the floating plate 200 can be urged upwardly by the pressure of liquid entering the dose reservoir 174 until the upper annular ridge 202 of floating plate 200 engages the stop.

As such, the patient can supplement the continuous dose rate by activating the bolus dose apparatus 15. If the dose reservoir 174 is full, the patient will receive a full dose of the beneficial agent. If, however, the patient activates the bolus dose apparatus 15 prior to the time required to fill the dose reservoir 174, the patient will receive a fraction of a dose. Because the dose reservoir 174 fills only at the bolus rate selected via the bolus flow restrictor means 300, this fraction is a linear function of the amount of time passed since the last bolus activation, up to the maximum bolus amount of dose reservoir 174.

It should be understood that various changes and modifications to the preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the scope of the present invention and without diminishing its attendant advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

## Claims

1. An apparatus for dispensing a fluid to an outlet, said apparatus comprising a source (24,30) of said fluid under pressure, first conduit means (18) connecting said source (24,30) in fluid communication with said outlet, bolus dose means (15) positioned in said first conduit means (18), said bolus means comprising a dose reservoir (174) in fluid communication with said source (24,30) and the outlet and having an upper volume limit which represents the discrete dose limit of the bolus dose means (15), and a control means (200,202,206,212,216,220) for providing a manually controllable bolus dose of the fluid from the reservoir (174) to said outlet, characterised by second conduit means (19) so connected in fluid communication with said source (24,30) and said outlet as to bypass the bolus dose means (15), and by first regulator means (16) provided in said second conduit means (19) for regulating a constant flow rate of the fluid under pressure to said outlet.
2. The apparatus of claim 1 wherein the first regulator means (16) includes a first flow regulator (64,70,250).
3. The apparatus of claim 1 or 2 wherein the source (24) of fluid comprises:
  - an elastomeric bladder (24) being capable of retaining fluid therein;
  - a housing (22) containing the elastomeric bladder (24); and the proximal end of said first conduit means (18) is connected in fluid communication with the elastomeric bladder (24).
4. The apparatus of any preceding claim wherein a second regulator means (300) is provided in said first conduit means (18) in fluid communication between said source (24) and said dose reservoir (174) for regulating the flow of fluid to the dose reservoir (174) at a constant flow rate up to the discrete dose limit of the bolus means (15).
5. The apparatus of claim 4 wherein the second regulator means (300) includes a second flow regulator (64,70,250).
6. The apparatus of claim 2 or 5 wherein each of said flow regulators (70,250) is contained on a single wafer (70,250).
7. The apparatus of anyone of claims 4 or 5 wherein the source (24) of fluid, the section of the second conduit means (18) upstream of the flow regulator of the first regulator means (16) and the section of the first conduit means (18) upstream of the flow regulator of the second regulator means (300) provide an approximate closed pressure system.
8. The apparatus of claim 1, wherein the fluid comprises a beneficial agent, the source (24) comprises an elastomeric bladder (24) capable of retaining the beneficial agent therein to create a pressurized source of the beneficial agent;
  - a catheter adapted for insertion into a patient is connected with the outlet; wherein the dose reservoir (174) is in fluid communication with the elastomeric bladder (24) and the downstream catheter, and the bolus dose means (15) comprises valve means (236) for preventing downstream flow of the beneficial agent, control means (200,202,206,212,216,220) being operable to open the valve means (236) and express the beneficial agent from the dose reservoir (174) to the catheter.
9. The apparatus of claim 8 wherein the elastomeric bladder (24) is contained in a housing (22) and includes means (28) for accepting fluid under pressure.

10. The apparatus of claim 10 8 or 9 further including a second flow regulator (300) in fluid communication with the elastomeric bladder (24) and the dose reservoir (174).
11. The apparatus of anyone of claims 4, 5 or 10 wherein the first and second flow regulator means (16,300) are arranged in parallel.
12. The apparatus of claim 10 or 11 wherein the first and second flow regulator means (16,300) are in the same housing.
13. The apparatus of claim 1, wherein the source (24) is a source of a beneficial agent, and the bolus dose means (15) is arranged in parallel with the flow regulator means (16).

#### Patentansprüche

1. Vorrichtung zur Abgabe eines Fluids an einen Auslaß, wobei die Vorrichtung aufweist: eine Druckfluidquelle (24, 30), eine erste Leitungseinrichtung (18), die die Quelle (24, 30) in Fluidverbindung mit dem Auslaß verbindet, eine Bolusdosiseinrichtung (15), die in der ersten Leitungseinrichtung (18) positioniert ist, wobei die Boluseinrichtung aufweist: ein Dosisreservoir (174) in Fluidverbindung mit der Quelle (24, 30) und dem Auslaß und mit einer oberen Volumengrenze, die die diskrete Dosisgrenze der Bolusdosiseinrichtung (15) repräsentiert, sowie eine Steuereinrichtung (200, 202, 206, 212, 216, 220), um eine manuell steuerbare Bolusdosis des Fluids aus dem Reservoir (174) an den Auslaß zu liefern, gekennzeichnet durch eine zweite Leitungseinrichtung (19), die so in Fluidverbindung mit der Quelle (24, 30) und dem Auslaß verbunden ist, daß sie die Bolusdosiseinrichtung (15) umgeht, und durch eine erste Regeleinrichtung (16), die in der zweiten Leitungseinrichtung (19) vorgesehen ist, um eine konstante Durchflußrate des Druckfluids zu dem Auslaß zu regeln.
2. Vorrichtung nach Anspruch 1, wobei die erste Regeleinrichtung (16) einen ersten Durchflußregler (64, 70, 250) aufweist.
3. Vorrichtung nach Anspruch 1 oder 2, wobei die Fluidquelle (24) aufweist: eine elastomere Blase (24), die fähig ist, Fluid darin zurückzuhalten; ein Gehäuse (22), das die elastomere Blase (24) enthält; und wobei das proximale Ende der ersten Leitungseinrichtung (18) in Fluidverbindung mit der elastomeren Blase (24) verbunden ist.

4. Vorrichtung nach einem der vorhergehenden Ansprüche, wobei eine zweite Regeleinrichtung (300) in der ersten Leitungseinrichtung (18) in Fluidverbindung zwischen der Quelle (24) und dem Dosisreservoir (174) vorgesehen ist, um den Fluiddurchfluß zu dem Dosisreservoir (174) mit einer konstanten Durchflußrate bis zu der diskreten Dosisgrenze der Boluseinrichtung (15) zu regeln.

5. Vorrichtung nach Anspruch 4, wobei die zweite Regeleinrichtung (300) einen zweiten Durchflußregler (64, 70, 250) aufweist.

6. Vorrichtung nach Anspruch 2 oder 5, wobei jeder Durchflußregler (70, 250) auf einer einzelnen Scheibe (70, 250) enthalten ist.

7. Vorrichtung nach einem der Ansprüche 4 oder 5, wobei die Fluidquelle (24), der Abschnitt der zweiten Leitungseinrichtung (18) an der Aufstromseite des Durchflußreglers der ersten Regeleinrichtung (16) und der Abschnitt der ersten Leitungseinrichtung (18) an der Aufstromseite des Durchflußreglers der zweiten Regeleinrichtung (300) ein annähernd geschlossenes Drucksystem bilden.

8. Vorrichtung nach Anspruch 1, wobei das Fluid ein gesundheitsförderndes Mittel aufweist, die Quelle (24) eine elastomere Blase (24) aufweist, die fähig ist, das gesundheitsfördernde Mittel darin zurückzuhalten, um eine Druckquelle des gesundheitsfördernden Mittels zu bilden; ein Katheter, der zum Einführen in einen Patienten ausgebildet ist, mit dem Auslaß verbunden ist; wobei das Dosisreservoir (174) in Fluidverbindung mit der elastomeren Blase (24) und dem abstromseitigen Katheter ist und die Bolusdosiseinrichtung (15) eine Ventileinrichtung (236) aufweist, um abstromseitigen Durchfluß des gesundheitsfördernden Mittels zu verhindern, wobei die Steuereinrichtung (200, 202, 206, 212, 216, 220) betätigbar ist, um die Ventileinrichtung (236) zu öffnen und das gesundheitsfördernde Mittel aus dem Dosisreservoir (174) in den Katheter auszupressen.

9. Vorrichtung nach Anspruch 8, wobei die elastomere Blase (24) in einem Gehäuse (22) enthalten ist und eine Einrichtung (28) aufweist, um Druckfluid aufzunehmen.

10. Vorrichtung nach Anspruch 8 oder 9, die ferner einen zweiten Durchflußregler (300) in Fluidverbindung mit der elastomeren Blase (24) und

dem Dosisreservoir (174) aufw ist.

11. Vorrichtung nach einem der Ansprüche 4, 5 oder 10, wobei die erste und die zweite Durchflußregleinrichtung (16, 300) parallel angeordnet sind. 5
12. Vorrichtung nach Anspruch 10 oder 11, wobei die erste und die zweite Durchflußregleinrichtung (16, 300) in dem gleichen Gehäuse sind. 10
13. Vorrichtung nach Anspruch 1, wobei die Quelle (24) eine Quelle eines gesundheitsfördernden Mittels ist und die Bolusdosiseinrichtung (15) parallel zu der Durchflußregleinrichtung (16) angeordnet ist. 15

#### Revendications

1. Appareil pour distribuer un fluide à une sortie, ledit appareil comprenant une source (24,30) de dit fluide sous pression, un premier conduit (18) connectant ladite source (24,30) en communication de fluide avec ladite sortie, des moyens de dosage de giclée (15) placés dans ledit premier conduit (18), lesdits moyens de dosage de giclée comprenant un réservoir de dose (174) en communication de fluide avec ladite source (24,30) et avec la sortie et ayant une limite supérieure de volume qui représente la limite de dose discrète des moyens de dosage de giclée (15), et des moyens de commande (200,202,206, 212,216,220) pour fournir une dose de giclée du fluide par commande manuelle, du réservoir (174) à ladite sortie, caractérisé en ce qu'il comprend un deuxième conduit (19), connecté en communication de fluide avec ladite source (24,30) et avec ladite sortie de façon à contourner les moyens de dosage de giclée (15), et un premier régulateur (16) prévu dans ledit deuxième conduit (19) pour réguler un débit constant du fluide sous pression, vers ladite sortie. 20 25 30 35 40
2. Appareil suivant la revendication 1, dans lequel le premier régulateur (16) comprend un premier régulateur d'écoulement (64,70,250). 45
3. Appareil suivant la revendication 1 ou 2, dans lequel la source (24) de fluide comprend : 50
  - un vessie en élastomère (24) capable de retenir un fluide à l'intérieur ;
  - un corps (22) contenant la vessie en élastomère (24) ; et 55
  - l'extrémité proche dudit premier conduit (18) est connecté en communication de fluide

avec la vessie en élastomère (24).

4. Appareil suivant une quelconque des revendications précédentes, dans lequel des deuxièmes moyens de régulation (300) sont prévus dans ledit premier conduit (18) en communication de fluide entre ladite source (24) et ledit réservoir de dose (174) pour réguler l'écoulement de fluide vers le réservoir de dose (174) à un débit constant, jusqu'à la limite de dose unitaire des moyens de dosage de giclée (15). 10
5. Appareil suivant la revendication 4, dans lequel les deuxièmes moyens de régulation (300) comprennent un deuxième régulateur d'écoulement (64,70,250). 15
6. Appareil suivant la revendication 2 ou 5, dans lequel chacun desdits régulateurs d'écoulement (70, 250) est contenu sur une pastille unique (70,250). 20
7. Appareil suivant une quelconque des revendications 4 ou 5, dans lequel la source de fluide (24), la partie du deuxième conduit (18) située en amont du régulateur d'écoulement des premiers moyens de régulation (16) et la partie du premier conduit (18) située en amont du régulateur d'écoulement des deuxièmes moyens de régulation (300) constituent un système sous pression sensiblement fermé. 25
8. Appareil suivant la revendication 1, dans lequel le fluide est un agent thérapeutique ;  
la source (24) comprend une vessie en élastomère (24) capable de retenir l'agent thérapeutique à l'intérieur pour créer une source sous pression de l'agent thérapeutique ;  
un cathéter prévu pour insertion dans un patient est connecté avec la sortie ;  
et dans lequel le réservoir de dose (174) est en communication de fluide avec la vessie en élastomère (24) et le cathéter aval, et les moyens de dosage de giclée (15) comprennent des moyens d'obturation (236) pour empêcher l'écoulement de l'agent thérapeutique en aval, les moyens de commande (200,202,206,212,216,220) étant manoeuvrables pour ouvrir les moyens d'obturation (236) et chasser l'agent thérapeutique du réservoir de dose (174) vers le cathéter. 30 35 40 45 50
9. Appareil suivant la revendication 8, dans lequel la vessie en élastomère (24) est contenu dans un corps (22) et comporte des moyens (28) pour recevoir un fluide sous pression. 55

10. Appareil suivant la revendication 8 ou 9, comprenant en outre un deuxième régulateur d'écoulement (300) en communication de fluide avec la vessie en élastomère (24) et le réservoir de dose (174). 5
11. Appareil suivant une quelconque des revendications 4, 5 ou 10, dans lequel les premiers et deuxièmes moyens de régulation d'écoulement (16,300) sont disposés en parallèle. 10
12. Appareil suivant la revendication 10 ou 11, dans lequel les premiers et deuxièmes moyens de régulation d'écoulement (16,300) sont dans le même boîtier. 15
13. Appareil suivant la revendication 1, dans lequel la source (24) est une source d'un agent thérapeutique, et les moyens de dosage de giclée (15) sont disposés en parallèle avec les 20  
moyens de régulation d'écoulement (16).

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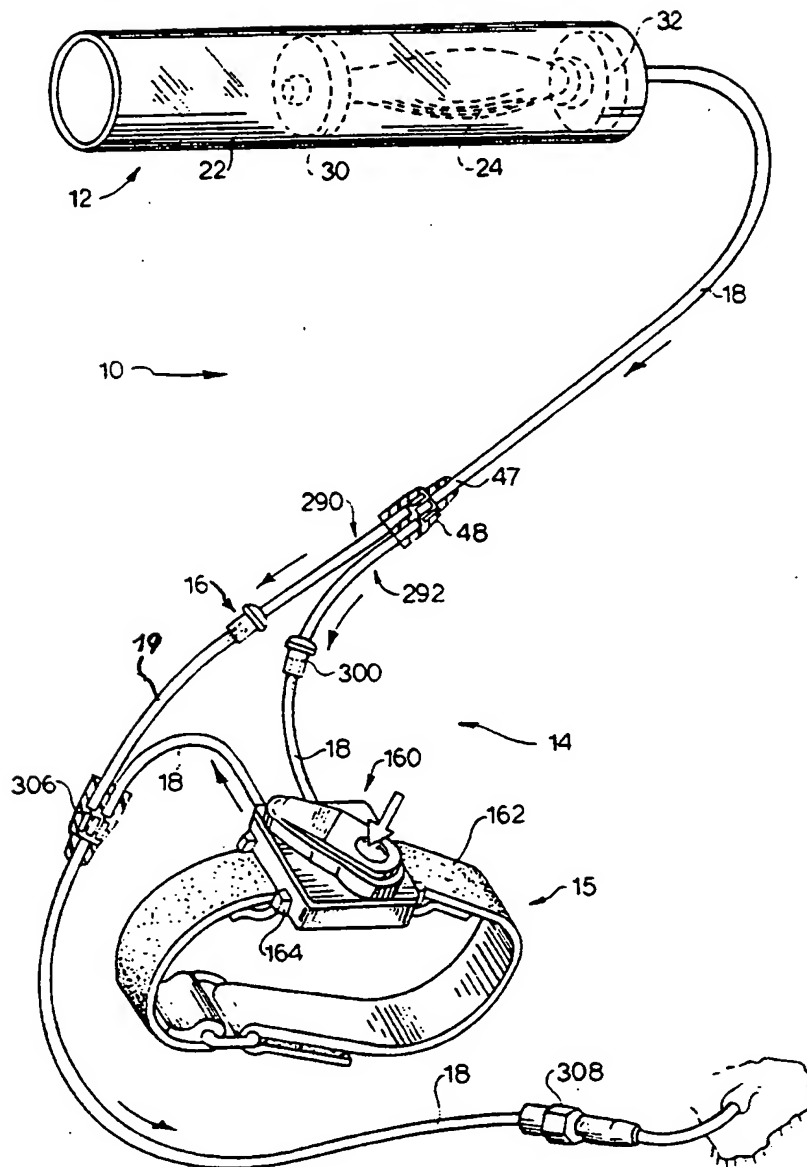
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FIG. 1



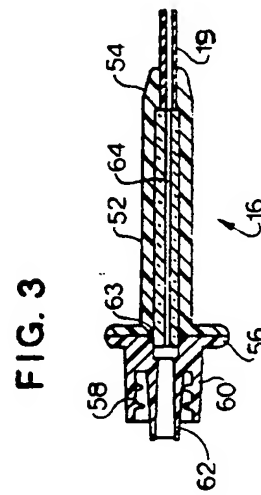
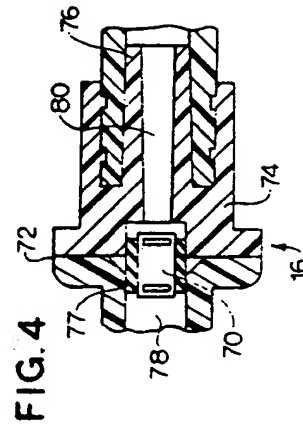
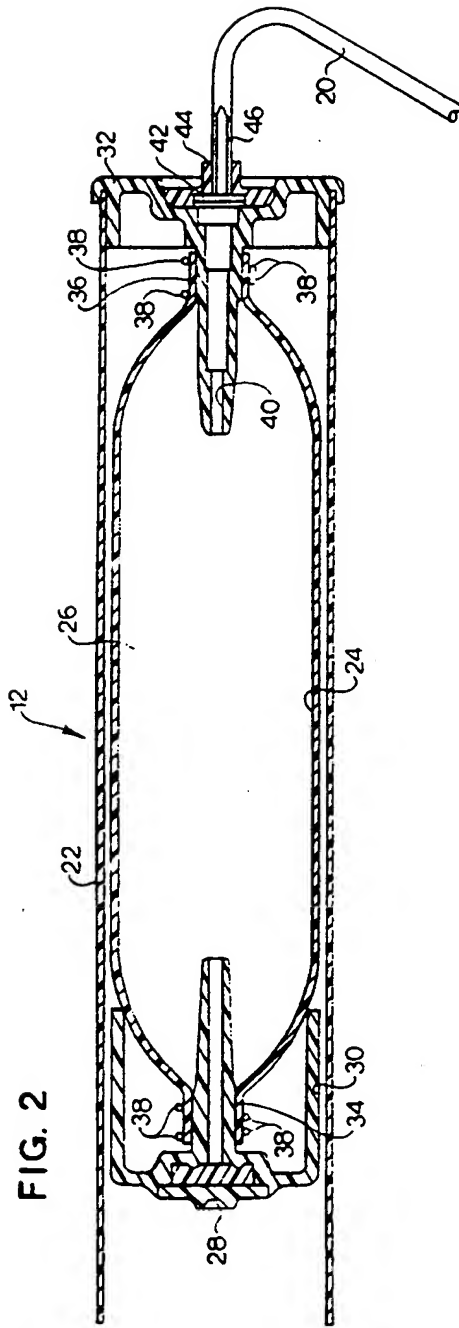


FIG. 5

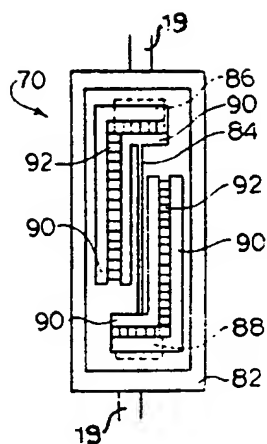


FIG. 10

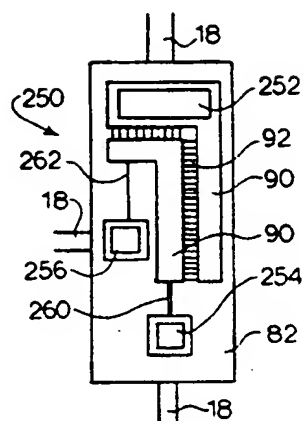
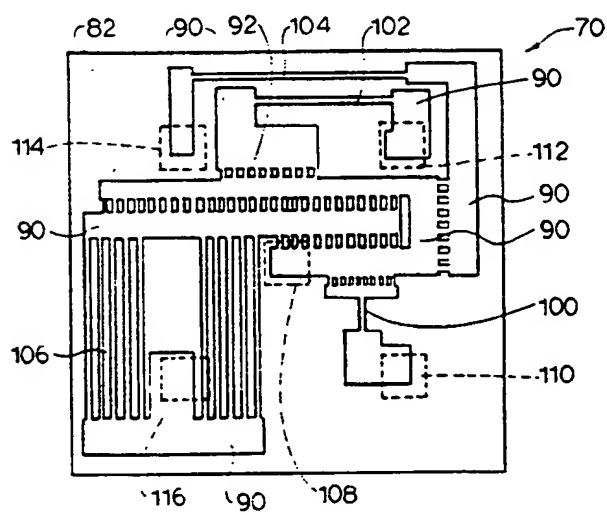
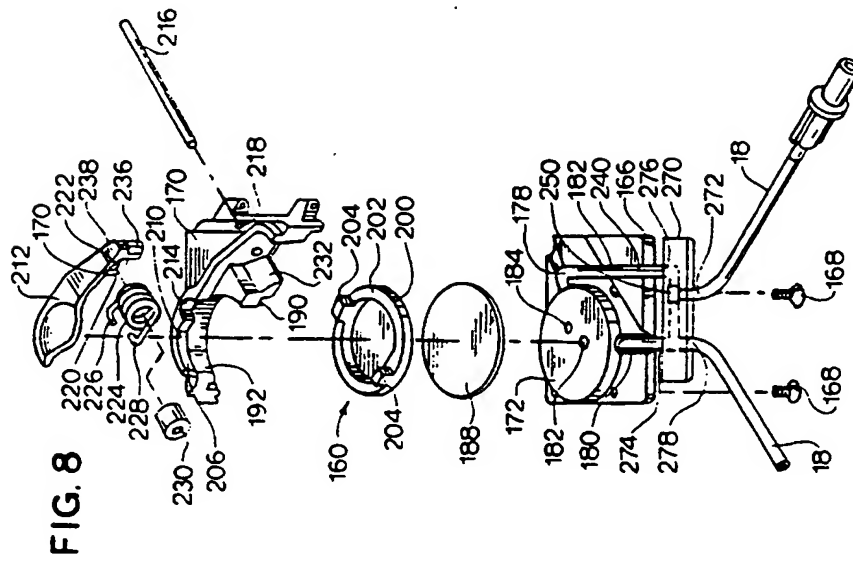
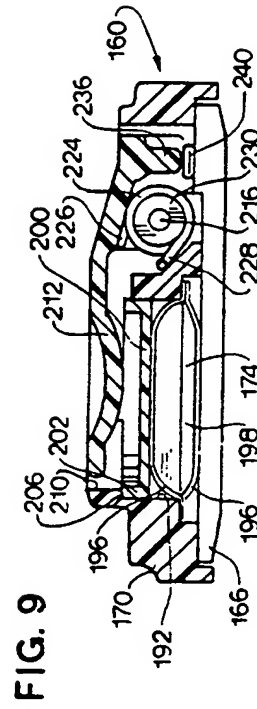
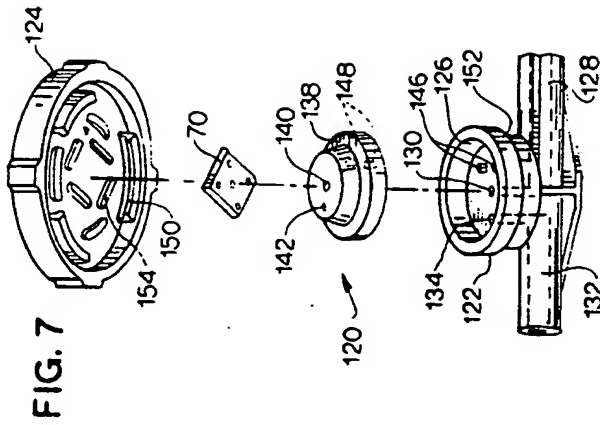


FIG. 6







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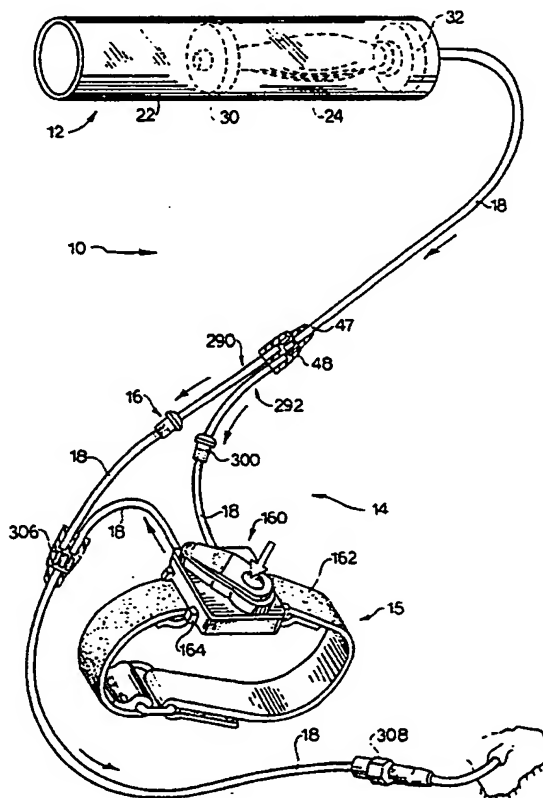
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(54) Title: CONTINUOUS/BOLUS INFUSOR

(57) Abstract

The present invention provides both a continuous dose and a bolus dose of fluid or beneficial agent (26) to a patient. A source of fluid (26) is in fluid communication with a continuous flow path (290) for providing the patient with a continuous source of the beneficial agent (26). The source of beneficial agent (26) is also connected to a bolus dose apparatus (15) which provides patient control of a bolus dose of the beneficial agent (26), up to a preselected maximum.



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CONTINUOUS/BOLUS INFUSORFIELD OF THE INVENTION

5

The present invention relates to the controlled delivery of fluids and, in particular, to a system and apparatus for the delivery of a preselected quantity of a beneficial agent to a patient.

10

BACKGROUND OF THE INVENTION

The controlled delivery of a preselected quantity of a beneficial agent to a patient is highly desirable in a number of situations. Particularly, the controlled delivery of drugs such as analgesics is highly desirable as there is great difficulty in properly administering analgesics. The need to administer analgesics varies greatly from patient to patient. Such factors as, for example, age, pain tolerance, renal function, and presence of other medications can all affect the pharmacokinetics of such analgesic.

In the area of analgesic administration, there has been much activity in the last several years directed towards letting the patient control how much drug he or she administers. It has been found that, as a group, patients controlling the quantity they receive use less analgesic than patients who must request the administration of a pain killer. One apparent factor is the psychological relief present when a

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patient knows he or she is in control of the amount of drug to be administered. The amount of drug the patient can self-administer must also be subject to a maximum level of drug.

5       The efficient patient controlled administration of drug has resulted in several devices on the market. Such devices generally suffer from several drawbacks. Initially, such devices are electromechanical in nature thus requiring an electrical power source. In addition, such devices are large  
10       and bulky which limits the patient's freedom to move.

Another drawback of such devices is that they only provide an on-demand rush of the drug as administered by the patient with no constant drug flow to the patient. While this type of  
15       drug administration is appropriate for many situations, it is often desirable to have a constant flow of drug to the patient, referred to herein as a continuous flow, supplemented by a patient controlled supplement of drug, referred to herein as a bolus flow. While several devices on the market are designed  
20       to provide such continuous flow supplemented by a patient controlled flow, such devices are again electro-mechanical in nature and are large and bulky thus limiting the patients' ability to move.

25       While, of course, two separate devices can be utilized to provide this continuous-bolus flow arrangement, such use of two devices adds to the cost and complexity of the system while further limiting patient mobility. What is thus needed is an apparatus and system for both a constant delivery of a

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beneficial agent and a patient controlled supplement of the beneficial agent which is low in cost, highly mobile, and easy to use. The present device meets these requirements.

5     BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a perspective view of a preferred embodiment of a device made in accord with the principles of the present invention;

10     FIGURE 2 is a cross-sectional view of the means for providing a source of fluid under pressure of the device of FIGURE 1;

15     FIGURE 3 is a cross-sectional view of a preferred embodiment of the flow regulator means of the device of FIGURE 1;

FIGURE 4 is a cross-sectional view of an alternative preferred embodiment of the flow regulator means;

FIGURE 5 is an enlarged overview of a preferred embodiment of the flow rate wafer of FIGURE 4;

20     FIGURE 6 is an enlarged overview of an alternative preferred embodiment of the flow rate wafer;

FIGURE 7 is an exploded perspective view of the selector housing for the flow rate wafer of FIGURE 6;

25     FIGURE 8 is an exploded, partially cut-away perspective view of a preferred embodiment of the bolus means of FIGURE 1;

FIGURE 9 is a cross-sectional view of an alternative preferred embodiment of the bolus means; and

FIGURE 10 is an enlarged overview of an alternative preferred embodiment of a flow rate wafer of the present invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Referring first to Figure 1, a completed assembly in  
accord with the present invention is designated generally by  
the reference numeral 10. The completed device generally  
includes means for providing a source of fluid under pressure  
12, bolus dose means for providing a controlled bolus dose of  
the fluid 14, and means for regulating a constant flow rate of  
fluid 16. Each means is in fluid communication by means such  
as flexible tubing 18 made of medical grade plastic such as,  
for example, polyvinyl chloride. Each tube segment connecting  
the various means acts as both a downstream conduit and an  
upstream conduit for the two means being connected. For  
example, the tubing segment 18 between the means for providing  
a source of fluid 12 and the controlled bolus dose means 14  
acts as a downstream conduit for the fluid source means 12 as  
well as an upstream conduit for the bolus dose means 14.

Referring now to Figure 2, a preferred embodiment of the  
means for providing a source of fluid under pressure 12 is  
seen. The presently preferred means is a device such as the  
Infusor sold by Baxter Healthcare Corporation (formerly  
Travenol Laboratories) of Deerfield, Illinois and shown in U.S.  
Patent No. 4,741,733 to Winchell et al, which is assigned to  
the assignee of the present invention and which disclosure is  
incorporated herein.

Such device includes a tubular housing 22. An elastomeric

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bladder 24 which is contained in the tubular housing 22 contains the fluid or beneficial agent 26 which is to be delivered.

5           The elastomeric bladder 24 of the assembly is self pressurized; that is, as a liquid such as the beneficial agent 26 is injected through means for receiving liquid under pressure, the elastomeric bladder 24 expands. The elastomeric bladder 24 exerts a substantially constant pressure on the  
10       fluid 26 throughout the volume range of the elastomeric bladder 24. The pressure within bladder 24 on the fluid 26 therein can preferably be about eight PSI.

          The bladder 24 is secured at a free end 34 to a floating  
15       piston 30. The floating piston 30 includes the means for receiving a liquid under pressure 28 so that the expandable bladder 24 can be filled. Such means can include a one-way valve contained in the housing having threaded receiving means for receiving a syringe absent a hypodermic needle for  
20       providing the fluid under pressure. Such means can alternately include a rubber membrane through which a syringe having a hypodermic needle can pierce to provide the fluid under pressure.

25           The bladder 24 is secured at a fixed end 36 to a plug 32 which is mounted to the housing 22. The plug 32 may be unitary with the housing 22. The free end 34 and fixed end 36 may be secured to the floating piston 30 and plug 32, respectively, by

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means of wire clamps 38, banding or the like. As fluid 26 is expressed from the expanded bladder 24, the floating piston 30 moves toward the plug 32. The plug 32 includes an aperture 40 extending therethrough which is in fluid communication with the inside of bladder 24.

A filter element 42 such as a polyester screen filter can be mounted across the aperture 40 to filter fluid 26 flowing out of bladder 24. The plug 32 may include an end piece 44 secured to the plug 32 by, for example, sonic welding to mount the filter element 42 within plug 32 and to secure the first segment tubing 18 to plug 32.

The tubing 18 includes a proximal end 46 and a distal end 47. The tubing proximal end 46 is secured to the end piece 44 of plug 32 by, for example, adhesive or the like. The distal end 47 is secured to a Y-connector 48, as will be explained in more detail below.

Referring now back to Figure 1, the means for regulating a constant flow rate of the fluid 16 and the bolus dose means for providing a controlled bolus dose of the fluid 14 are seen. The means for regulating a constant flow rate of the fluid 16 is in fluid communications with the means for providing a source of fluid under pressure 12 via the tubing 18.

Referring now to Figure 3, a preferred embodiment of the flow regulator means 16 of the present invention is seen. Such



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flow regulator means is also shown in U.S. Patent No. 4,741,733 to Winchell et al. The flow regulator means 16 includes regulator housing 52 having a flow regulator 64 dispensed therein. The regulator housing 52 is secured at an inlet  
5 passage 54 to tubing 18 extending from the Y-connector 48 by, for example, solvent bonding about the outside diameter of tubing 18.

Opposite the inlet passage 54, the regulator housing 52  
10 includes an enlarged outlet passage 56 forming an annular flange with and being connected to an internally threaded sleeve 58 of a locking Luer 60. The Luer lock 60 includes a Luer taper element 62 which is adapted for connection with a female Luer contained on a downstream tube segment.

15 A sealing element such as an O-ring 63 is disposed around the periphery of flow regulator 64 to prevent fluid from flowing between the outside of regulator 64 and regulator housing 52. The O-ring 63 is mounted in an annular channel  
20 around the periphery of flow regulator 64. The channel has a triangular cross section. The three sides of the channel are formed by the flow regulator 64, a beveled corner of the enlarged end of housing 52 and the threaded sleeve 58 of the connecting means.

25 The O-ring 63 is pressed within and conforms to the shape of the channel as the channel is formed. The channel is formed when the threaded sleeve 56 and the enlarged end of housing 52

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are secured together by means such as, for example, sonic welding. The pressure placed on the sealing element 64 by the threaded sleeve 58 and the enlarged end of housing 52 deforms the O-ring 62 substantially into the shape of the channel  
5 thereby effectively sealing the flow regulator 64 and the housing 52. Thus, different length flow regulators 64 can be utilized in the housing 52.

10 In a preferred embodiment, the flow regulator 64 includes a capillary-type flow restrictor. One such capillary-type flow restrictor can be made of glass which defines a very small bore in fluid communication with the tubing.

15 The fluid flow rate through the tubing 18 is determined by the characteristics of the capillary-type flow restrictor along with the characteristics of the fluid which flows through the flow restrictor. In a glass bore flow restrictor, the flow rate can be changed by varying the cross-sectional area and length of the regulator bore.

20 In a second preferred embodiment, the flow regulator includes a flow restrictor chip or wafer encapsulated in housing. Such a device is shown in U.S. Application Serial No. 167,822 to Winchell et al. which is assigned to the assignee of  
25 the present invention which disclosure is incorporated herein. Referring to Figure 4, this alternative preferred embodiment is seen in detail.

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The flow restrictor chip 70 is contained in housing 72 which includes a locking Luer 74 contained at the end of tubing. The Luer lock 74 includes a Luer taper element 76 adapted for connection with a female Luer contained on  
5 downstream tubing.

A seal member 77 is located between an inlet passage 78 and an outlet passage 80 . The wafer or chip 70 is carried within seal member 77 with the wafer 70 having an inlet in  
10 fluid communication with the inlet passage 78 and the wafer 70 having an outlet in fluid communication with the outlet passage 80. All fluid traversing the housing 72 must pass through the flow restrictor path of wafer or chip 70. The wafer or chip 70 thus serves to regulate the flow rate of the fluid.

15 Referring now to Figure 5, a preferred embodiment of the wafer or chip 70 is seen in detail. The wafer 70 includes a base substrate 82 into which one or more flow restrictor paths 84 are formed. These paths can be of various geometrics such  
20 as V-shaped, arcuately shaped or rectangularly shaped, depending on the nature of the substrate and the etching technique utilized. In the illustrated embodiment, a single main flow restrictor path 84 is formed having a preselected discrete resistance to fluid flow.

25 The path may be enclosed by various means such as an overlay (not seen) covering the base substrate 82 to enclose the restrictor path 84. The inlet 86 and outlet 88 of wafer 70 are formed as apertures in base substrate 82 which form fluid

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communication paths at opposite ends of flow restrictor path 84.

5       Manifold regions 90 can also preferably be preformed on the base substrate 82 at opposite ends of flow restrictor path 84 to assure a non-restricted flow on the wafer 70. Also, a plurality of secondary flow restrictor paths 92, with each secondary flow restrictor path 92 smaller than the main flow restrictor path 84, can be provided to filter out small particulate matter during passage across the wafer 70.

10

      In an alternative embodiment of the presently preferred flow control means 14, a wafer or chip 70 having at least two independent flow restrictor paths formed on the base substrate can be utilized. Such a wafer is seen in Figure 6 in which  
15       four flow restrictor paths are seen.

      In this embodiment, the four restrictor paths 100, 102, 104, 106 are formed between a central wafer inlet 108 and first 110, second 112, third 114 and fourth 116 restrictor outlets.  
20       Each path is formed with a preselected cross sectional area and length to provide a different resistance to flow. Fluid transversing each flow restrictor path will therefore flow at a different, preselected flow rate.

25       The wafer again includes fluid manifolds 90 formed in association with each flow restrictor path 100, 102, 104, 106,. In addition, filtration areas 92 can also once again be formed.

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The multi-path flow restrictor chip is contained in selector housing 120. Referring to Figure 7, the selector housing 120 is seen in detail. The selector housing 120 includes a base member 122 and a selector member 124 which is normally carried on the base member 122. The base member 122 includes a well 126. An inlet passage 128 communicates with the well 126 by means of an inlet port 130. An outlet passage 132 also communicates with the well 126 by means of an outlet port 134. The inlet 128 and outlet 132 passages are in fluid communication with tubing 18.

The inlet port 130 is located generally along the centerline of well 126. The outlet port 134 is radially spaced a selected distance from the inlet port 130. An elastomeric seal member 138 occupies the well 126. The seal member 138 includes first 140 and second 142 apertures which extend through the body of seal member 138. When the seal member 138 is properly positioned in well 126, the first aperture 140 registers with the inlet port 130 and the second aperture 142 registers with the outlet port 134. A pair of locating pins 146 are positioned in well 126 which mate with a pair of locating holes 148 in seal member 138 to align and retain the seal member 138 in the desired position in well 126.

The selector member 124 is rotatable on the base member 122 about an axis generally aligned with the centerline of well 126. The selector member 124 can be rotatably attached to the

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base member 122 by various means, such as by rotatably affixing by snap-fit engagement between a circumferential flange 120 on the selector member 124 and a mating circumferential ridge 152 on the base member 122.

5

The flow restrictor wafer 70 is carried by the selector member 124. More particularly, projecting ridges 154 formed within the inner wall of selector member 124 define a space generally corresponding to the shape of wafer 70. The wafer 70 is carried within this space with the ridges 154 contacting the peripheral edges of wafer 70 and preventing lateral movement of wafer 70.

10

As such, the wafer inlet 108 is in alignment with the inlet port 130 of base member 122 via the first aperture 140 in seal member 138. As the wafer 70 is carried for movement in common with the selector member 124, the inlet 108 of wafer 70 stays in alignment with the inlet port 130. This rotation also serves to place the various outlets 110, 112, 114, 116 of wafer 70 into and out of alignment with the outlet port 134 of base member 122 via the second aperture 142 in seal member 138, depending on the position of the selector member 124 within its circular path. As such, different flow rates can be selected in this embodiment by simply rotating the selector member 124.

15

20

25

Referring now back to Figure 1, the means 14 for providing a controlled bolus dose of the fluid is seen. Such controlled bolus dose means is shown in U.S. Application Serial No.

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308,972 to Winchell et al. which is assigned to the assignee of the present invention and which disclosure is incorporated herein.

5           The preferred embodiment of the controlled bolus dose means 14 includes a bolus dose apparatus 15 which includes housing 160 which can be worn in the same manner as a wristwatch. The housing 160 can include wristband portions 162 secured to the housing 160 by mounting pins 164 to which the  
10 wristband portions 162 are secured.

Referring now to Figures 8 and 9, the housing 160 of bolus dose apparatus 15 is seen in detail. The housing 160 includes a back plate 166 secured by securing means such as screws 168  
15 to a casing 170. Alternatively, the back plate 166 can be permanently secured by means such as sonic welding. A portion of back plate 166 can include a raised plateau 172 that forms one wall of a dose reservoir 174. A dose reservoir inlet 176 and a dose reservoir outlet 178 are formed within back plate  
20 166. The inlet 176 includes a channel portion 180 and a bore portion 182 in fluid communication with the channel portion 180 and the interior of dose reservoir 174. The upstream tubing 18 is secured into the bore portion 180 by means such as friction fit or solvent bonding. The channel portion serves as a track  
25 to trap the conduit in a fixed location when the back plate 166 is secured to the casing 170.

The dose reservoir outlet 178 includes an outlet channel portion 182 and an outlet bore portion 184 in fluid

-14-

communication with the interior of dose reservoir 174 and outlet channel portion 182. The downstream tubing 18 is secured to the outlet bore 182 by means such as a friction fit or solvent bonding.

5

The dose reservoir 174 includes an enclosed flexible container which can be compressed to force expulsion of the contents of dose reservoir 174. In one embodiment, this dose reservoir 174 can be a circular flexible sheet 188 placed on top of raised plateau 172 of back plate 166. The periphery of circular flexible sheet 188 rests on the periphery of raised plateau 172. The circular flexible sheet 188 may be made of, for example, polyisoprene rubber material.

15

The dose reservoir 174 can be formed by utilizing a pressure seal structure in the housing to press the flexible sheet 188 adjacent to its outer periphery against the raised plateau 172 creating a fluid tight seal between the flexible sheet 188 and the plateau 172. More particularly, the casing 170 can include a downwardly extending annular rib 190 disposed below and outwardly of a guide bore 192 so that the annular rib 190 is directly above the periphery of flexible sheet 188 and raised plateau 172. When the back plate 166 is secured to the casing 170 such as with the screws or sonic welding, the periphery of flexible sheet 188 is trapped between the annular rib 190 and the raised plateau 172.

25

In an alternative embodiment, seen in Figure 9, the dose reservoir 174 can include two flexible sheets 196 sealed



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together about the outer periphery of each to define a pillow 198. This pillow 198 is the enclosed flexible container contained in casing 170. The two flexible sheets 196 can be made of, for example, vinyl. The outer periphery seal includes  
5 apertures through which the upstream and downstream tubing extends to establish fluid communication with the inside of pillow 198. In this alternative embodiment, the back plate 166 need not include a raised plateau.

10 The control means of the apparatus includes dose reservoir compression means which in a preferred embodiment includes a floating plate 200 that rests on top of flexible sheet 188 or pillow 198 and has a diameter less than the diameter of guide  
15 bore 192. The floating plate 200 can include an upper annular ridge 202 projecting from the top side of floating plate 200 at its periphery. The floating plate 200 can further include two volume indicator pegs 204 projecting from the upper annular ridge 202.

20 A casing ridge 206 projects inwardly from the guide bore 192 at the top of guide bore 192 and acts as a stop that is part of the dose compression means. The floating plate 200 travels in a direction perpendicular to the back plate 166, the stop serving as an upper limit for the floating plate 200 when  
25 the upper annular ridge 202 thereof engages the stop.

The casing 170 defines an opening 210 for the control switch 212. Part of opening 210 is directly above the guide bore 192 and the floating plate 200. The defined opening 210

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of casing 170 includes slots 214 in which the volume indicator pegs 204 of floating plate 200 travel as the floating plate 200 reaches its upper limit.

5       The control switch 212 is rotatably mounted upon a cylindrical pin 216 mounted in receiving sockets 218 within casing 170. The control switch 212 includes two mounting flanges 220 each having a pin opening 222 through which the pin 216 extends.

10

      The control switch 212 rotates within a narrow arc about the axis of pin 216. A coil-type spring 224 is also mounted about the pin 216 between the mounting flanges 220. The pin 216 extends through the inside of coil-type spring 224. The  
15       spring 224 includes contact ends 226, 228. A spacer 230 is mounted on the pin 216 between the coil-type spring 224 and the pin 216. The contact ends 226, 228 tend to move circumferentially relative to the axis of pin 216 and the axis of coil-type spring 224.

20

      The contact end 226 contacts and urges against the underside of control switch 212. The second contact end 228 contacts and urges against a shelf 232 in casing 170. The coil-type spring 224 thus serves as biasing means of the  
25       apparatus.

      The control switch 212 can also include a blunt end conduit occlusion bar 236 made integrally with the control

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switch 212 and forming a single rigid part. The conduit occlusion bar 236 depends downwardly from the valve end 238 of control switch 212. The conduit occlusion bar 236 acts with the flexible wall portion 240 of downstream tubing 18 to form valve means for the apparatus.

Referring now to Figure 10, another alternative preferred embodiment of the flow rate wafer is seen. This alternative embodiment is referred to herein as a dual wafer 250. This embodiment includes a wafer inlet 252, a continuous flow outlet 254, and a bolus flow outlet 256. The wafer 250 can include a fluid manifold 90 formed in association with the wafer inlet 252. In addition, a filtration area 92 can also be provided in association with the wafer inlet 252.

The wafer inlet 252, fluid manifold 90, and filtration area 92 are in fluid communication with both a continuous restrictor path 260 and a bolus restrictor path 262. The restrictor paths 260, 262 are formed with a preselected cross-sectional area and length to provide different restriction to flow. Fluid transversing the two flow paths 260, 262 will therefore flow at different preselected flow rates. The continuous restrictor path 260 is in fluid communication with the continuous flow outlet 254 while the bolus restrictor path 262 is in fluid communication with the bolus flow outlet 256.

Referring back to Figure 8, housing 270 for the dual wafer 250 of Figure 10 is seen in conjunction with the housing 160 of

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bolus dose apparatus 15. The housing 270 includes two inlet ports 272, 274 and two outlet ports 276, 278. The first housing inlet port 272 is in fluid communication with the means for providing a source of fluid under pressure 12 by means of tubing 18. The first housing inlet port 272 is thus connected to tubing 18 by means such as an adhesive. The first housing inlet port 272 is in fluid communication with the dual wafer inlet 252. As such, fluid enters the housing 270 through the first housing inlet port 272 and then flows through the dual wafer inlet 252 to the fluid manifold 90 of dual wafer 250. After flowing through the filtration area 92, the fluid flows in parallel through the continuous restrictor path 260 and the bolus restrictor path 262.

The first housing outlet 276 is in fluid communication with the bolus flow outlet 256 of dual wafer 250. The first housing outlet 276 is also in fluid communication with the input of bolus dose apparatus 15 by means such as tubing 18. The second housing input 274 is in fluid communication with the outlet of bolus dose apparatus 15. The second housing outlet 278 is in fluid communication with both the continuous flow outlet 254 of dual wafer 250 and the second housing input 274. The second housing outlet 278 is also in fluid communication with downstream tubing 18. The continuous fluid flow passes through the continuous restrictor path 260 to the second housing outlet 278. The bolus fluid flow passes through the bolus restrictor path 262 to the bolus dose apparatus 15, then from the bolus dose apparatus 15 to the housing second input 274, and then to the housing second outlet 278.

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Referring again to Figure 1, the operation of the device will be described. As previously seen, the means for providing a source of fluid under pressure 12 can preferably provide the fluid or beneficial agent at a pressure of about eight PSI. In one embodiment, this beneficial agent under the flow rate pressure is split into two flow paths by a Y-connector 48. The two flow paths are a continuous flow path 290 and a bolus flow path 292. The continuous flow path 290 leads to a constant flow regulator means 16. The bolus flow path 292 leads to a bolus flow regulator means 300 which in the preferred embodiment can include the same type flow restrictor as the constant flow regulator means 16, be it the glass capillary type, the wafer type, or the multi-channel adjustable wafer type.

In the alternative embodiment, the means for providing a source of fluid under pressure 12 is provided to the inlet 252 of dual wafer 250. The continuous flow path 290 is thus formed by the continuous restrictor path 260 while the bolus flow path 292 is formed by the bolus restrictor path 262.

The means for providing a source of fluid under pressure 12 and tubing 18 up to the two flow regulators define an approximate closed pressure system. This is because the flow rate through the flow restrictors is sufficiently small to maintain the closed pressure system at about eight PSI. As such, the fluid pressure at the inlet of the fluid flow restrictors of the present device remains at about eight PSI.

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It has been found that by keeping a closed pressure system and utilizing two flow restrictors in such parallel arrangement, no lag time is experienced. Lag time is that amount of time needed in series flow restrictors to replenish the pressure upstream of the constant flow restrictor after a bolus dose is administered.

In the continuous flow path 290, the flow rate pressure is supplied to the constant flow regulator means 16. The beneficial agent then flows through the constant flow regulator means 16 which governs the rate of flow of the fluid. In a preferred example, the continuous flow rate is set at about 0.5 ml per hour of the beneficial agent as determined by the length and diameter of the capillary bore.

From the outlet passage of the constant flow regulator means 16, in the first embodiment, tubing 18 is connected in direct fluid communication with a downstream Luer 308 by means such as, for example, a second Y-connector 306. In the alternative embodiment, the second housing outlet 278 of dual wafer housing 270 is directly connected to the downstream Luer 308 as a Y-type configuration is built into the housing 270. The downstream Luer 308 is adapted to be connected to a catheter for introduction into a patient's vein.

The bolus flow path 292 is also supplied to the bolus dose means 14 by an inlet passage of a bolus flow regulator means 300. In this second flow regulator means, the flow regulator

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sets the rate at which the bolus means dose reservoir 174 fills with fluid. In a preferred example, the bolus flow regulator means 300 is set at about 2.0 ml per hour. This rate plus the continuous flow rate represents the total discrete dose amount  
5 volume limit above which the patient will not be able to receive the beneficial agent. In the preferred example, the total discrete amount is about 2.5 ml per hour.

The outlet passage of bolus flow regulator means 300 is  
10 connected to the inlet passage of bolus dose apparatus 15 by means such as tubing 18. Thus, the bolus flow regulator means 300 and the bolus dose apparatus 15 form the means for providing a controlled bolus dose of the fluid 14. The bolus flow rate fills the dose reservoir 174 to its maximum volume as  
15 defined and limited by the floating plate and the stop, which in a preferred example is approximately 0.5 ml. This maximum volume represents the bolus dose discrete dose limit. The bolus flow rate expands the dose reservoir 174 over time in a linear manner to the maximum volume. As such, if the bolus  
20 dose is administered prior to the filling of dose reservoir 174, the amount of bolus dose administered is a linear function of the amount of time which has passed since the last bolus dose up to the time when the dose reservoir 174 is filled to its maximum volume thus attaining the bolus dose discrete dose  
25 limit.

The spring 224 biases the valve end of control switch 212, including the conduit occlusion bar 236, downwardly. The spring 224 also biases the end opposite the valve end of control switch 212 upwardly so that the control switch 212,

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although remaining within the defined opening of casing 270, is spaced from the floating plate 200. The flexible wall portion 240 of the downstream apparatus conduit is disposed directly underneath the conduit occlusion bar 236.

5

To activate the controlled bolus means dose, the patient pushes the upwardly biased end of control switch 212. This causes the control switch 212 end to contact the floating plate 200 and depress it downwardly out of engagement with the stop  
10 and compress the dose reservoir 174 by urging the flexible sheet 188 against the raised plateau 172 or the pillow 198 against the back plate 166. Before contact between the upwardly biased end of control switch 212 and floating plate 200 is made, the biasing force provided by the spring 126 is  
15 overcome by the force of the control switch 212 activation, lifting the valve end and the conduit occlusion bar 236 out of engagement with the flexible wall portion 240 of the downstream conduit thus placing the valve means in an open, operating mode.

20

As the floating plate 200 is urged downwardly by the control means, the dose of beneficial agent within dose reservoir 174 is expressed out of the dose reservoir 174, through the outlet. In one embodiment, the outlet is connected to downstream tubing which is connected to the second  
25 Y-connector 306 to establish direct fluid communication with the downstream Luer 308 and catheter. In a second embodiment, the outlet is connected to the dual wafer second housing input 274 which acts as the Y-connector and is in fluid communication with to the downstream Luer 308.



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After the control switch 212 has been released by the patient, the flexible wall portion 240 of the downstream apparatus conduit is once again occluded by the blunt-ended conduit occlusion bar 236, thus placing the valve means in the closed mode of operation. In addition, the biasing spring 224 has returned the button end of the control switch to its inactivated, upper position. In this state, the floating plate 200 can be urged upwardly by the pressure of liquid entering the dose reservoir 174 until the upper annular ridge 202 of floating plate 200 engages the stop.

As such, the patient can supplement the continuous dose rate by activating the bolus dose apparatus 15. If the dose reservoir 174 is full, the patient will receive a full dose of the beneficial agent. If, however, the patient activates the bolus dose apparatus 15 prior to the time required to fill the dose reservoir 174, the patient will receive a fraction of a dose. Because the dose reservoir 174 fills only at the bolus rate selected via the bolus flow restrictor means 300, this fraction is a linear function of the amount of time passed since the last bolus activation, up to the maximum bolus amount of dose reservoir 174.

It should be understood that various changes and modifications to the preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and

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scope of the present invention and without diminishing its attendant advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

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## WHAT IS CLAIMED IS:

1. An apparatus for dispensing a fluid comprising:  
means for providing a source of fluid under pressure;  
means in fluid communication with the source of fluid for  
5 regulating a constant flow rate of the fluid;  
bolus dose means also in fluid communication with the  
source of fluid for providing a controllable bolus dose of the  
fluid; and  
downstream tubing means in fluid communication with the  
10 regulating means and the bolus dose means.
2. The apparatus of claim 1 wherein the regulator means  
includes a flow regulator.
- 15 3. The apparatus of claim 1 wherein the means for  
providing a source of fluid comprises:  
an elastomeric bladder being capable of retaining fluid  
therein;  
a housing containing the elastomeric bladder; and  
20 tubing having a proximal end in fluid communication with  
the elastomeric bladder and a distal end in fluid communication  
with both the regulator means and the bolus dose means.

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4. The apparatus of claim 1 wherein the bolus dose means comprises:

a dose reservoir in fluid communication with the means for providing a source of fluid and the downstream tubing means, the dose reservoir having an upper volume limit which represents the discrete dose limit of the bolus dose means; and control means for expressing the fluid in the dose reservoir from the dose reservoir to the downstream fluid communication means.

5. The apparatus of claim 4 wherein the bolus dose means further includes a flow regulator in fluid communication with the means for providing a source of fluid and the dose reservoir for regulating the flow of fluid to the dose reservoir at a constant flow rate up to the discrete dose limit of the bolus means.

6. The apparatus of claim 5 wherein the regulating means also includes a flow regulator.

7. The apparatus of claim 6 wherein the flow regulator of the bolus dose means and the flow regulator of the regulator means are in parallel.

8. The apparatus of claim 6 wherein the flow regulator of the bolus dose means and the flow regulator of the regulator means are contained on a single wafer.

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9. The apparatus of claim 6 wherein the means for providing a source of fluid and the tubing means up to the flow regulator of the regulator means and the flow regulator of the bolus dose means are an approximate closed pressure system.

5

10. An apparatus for dispensing a beneficial agent to a patient comprising:

an elastomeric bladder capable of retaining the beneficial agent therein to create a pressurized source of the beneficial agent;

10

flow regulator means in fluid communications with the elastomeric bladder and a downstream catheter, the downstream catheter adapted for insertion into the patient; and

a dose reservoir also in fluid communication with the elastomeric bladder and the downstream catheter, the dose reservoir having valve means for preventing downstream flow of the beneficial agent and control means for opening the valve means and expressing the beneficial agent from the dose reservoir downstream.

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11. The apparatus of claim 10 wherein the elastomeric bladder is contained in a housing and includes means for accepting fluid under pressure.

25

12. The apparatus of claim 10 further including a flow regulator in fluid communication with the elastomeric bladder and the dose reservoir.

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13. The apparatus of claim 12 wherein the flow regulator means and the flow regulator are in parallel.

5 14. The apparatus of claim 12 wherein the flow regulator means and the flow regulator are in the same housing.

10 15. The apparatus of claim 10 wherein the dose reservoir has an upper volume limit which represents the discrete dose limit of the dose reservoir.

16. An apparatus adapted to be connected to a source of beneficial fluid for delivery of the beneficial fluid to a patient comprising:

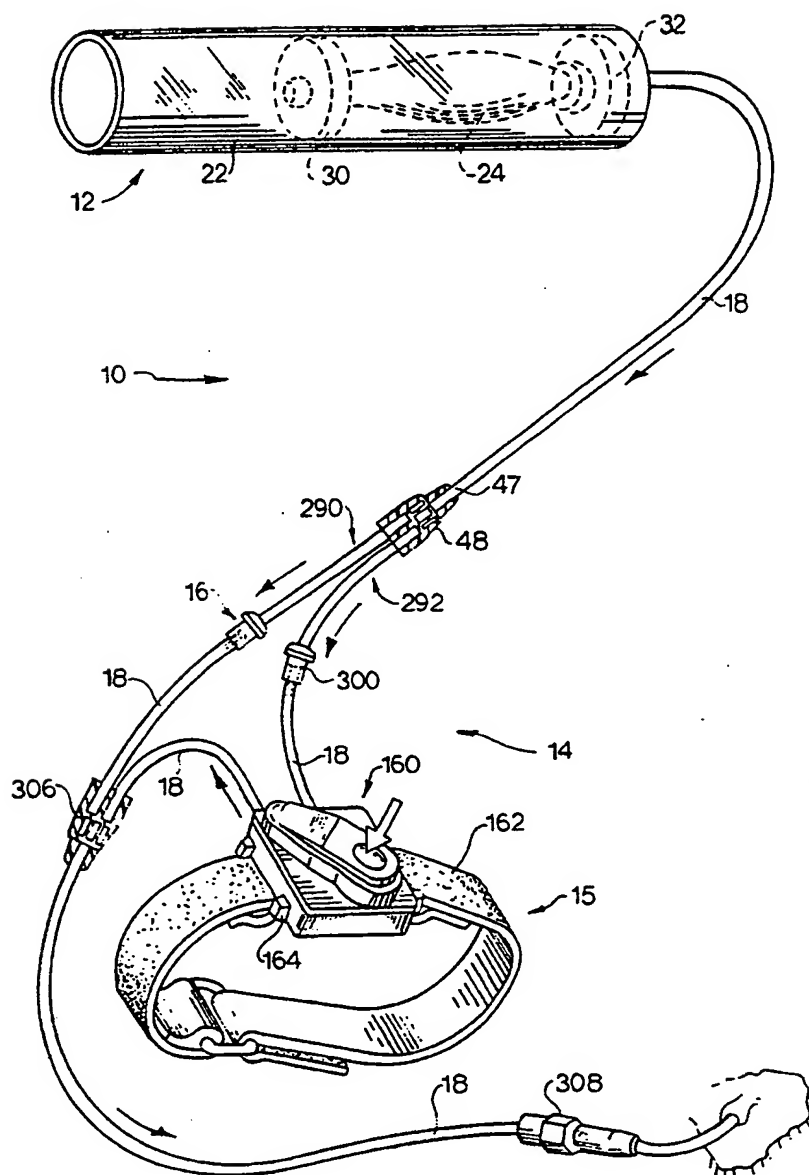
15 upstream tubing adapted to establish fluid communications with the source of beneficial fluid;

20 a flow regulator in fluid communications with the upstream tubing and downstream tubing, the downstream tubing adapted for connection to the patient; and

25 bolus dose means in fluid communications with the upstream tubing and the downstream tubing for providing a controllable bolus dose of the beneficial agent, the bolus dose means being in parallel with the flow regulator.

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FIG. 1



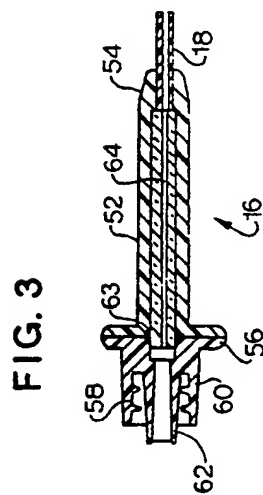
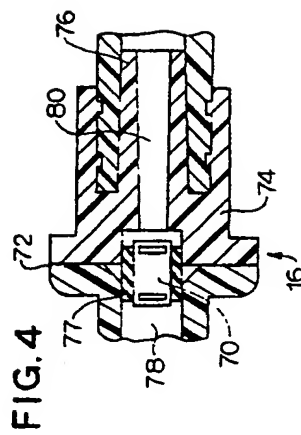
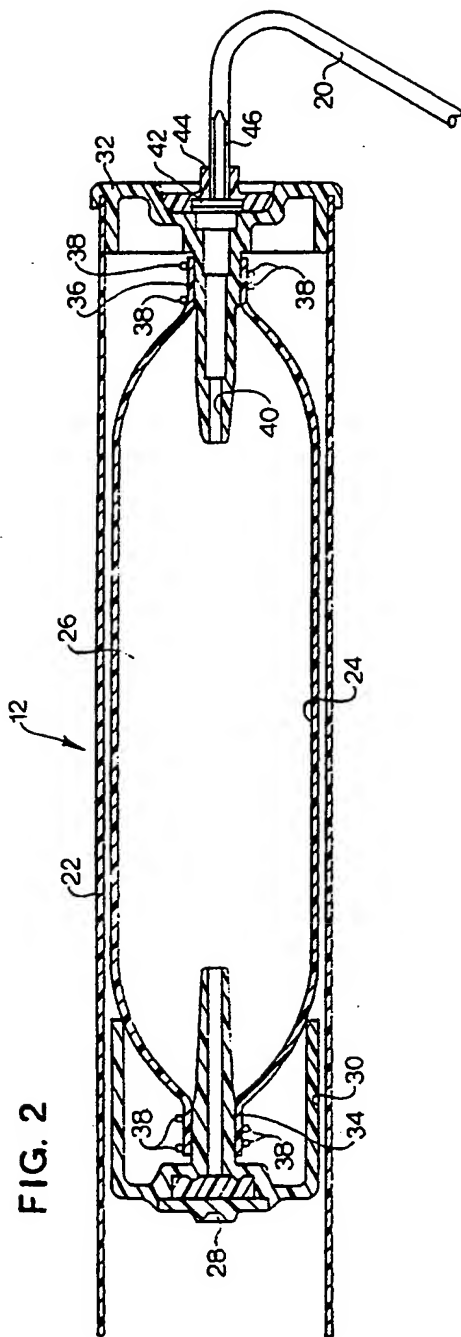




FIG. 5

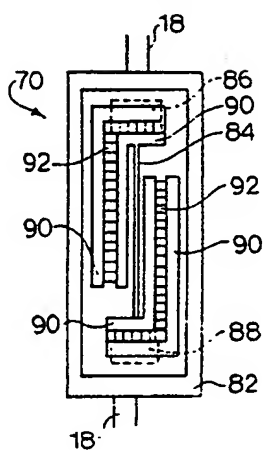


FIG. 10

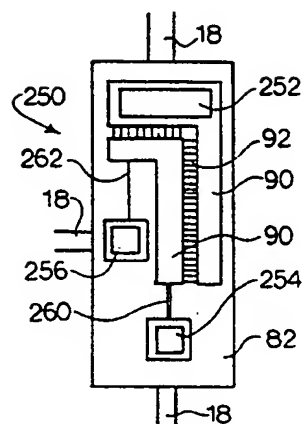
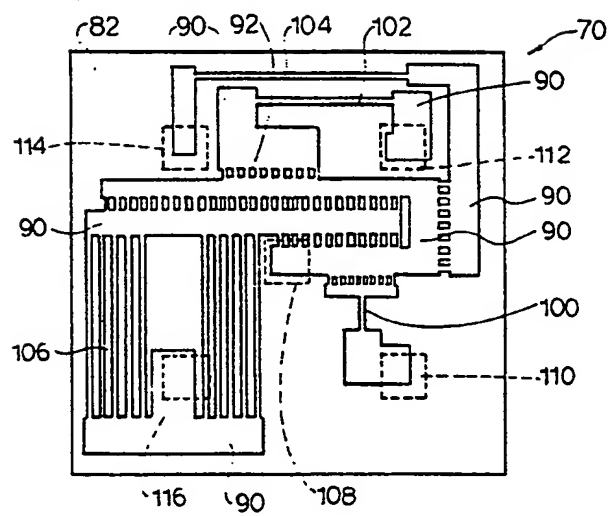
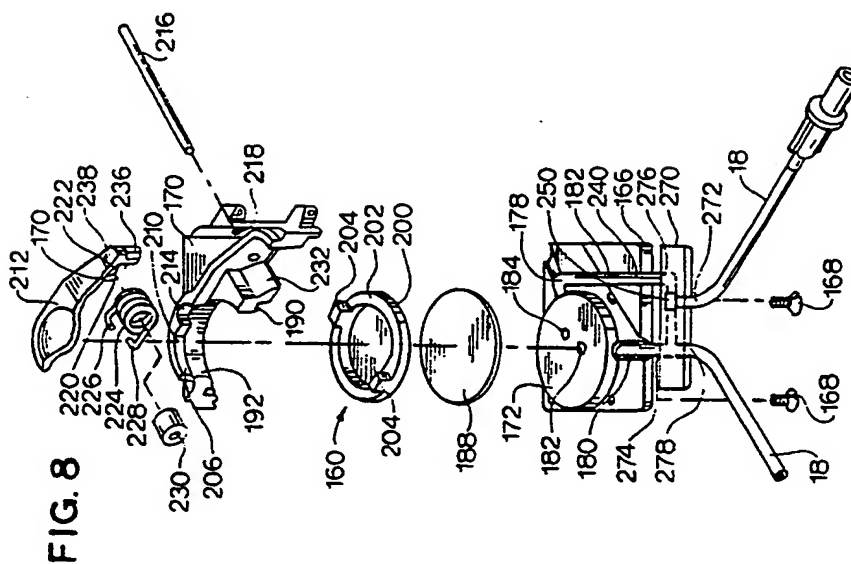
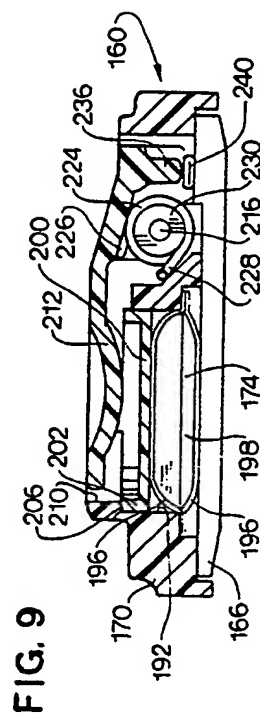
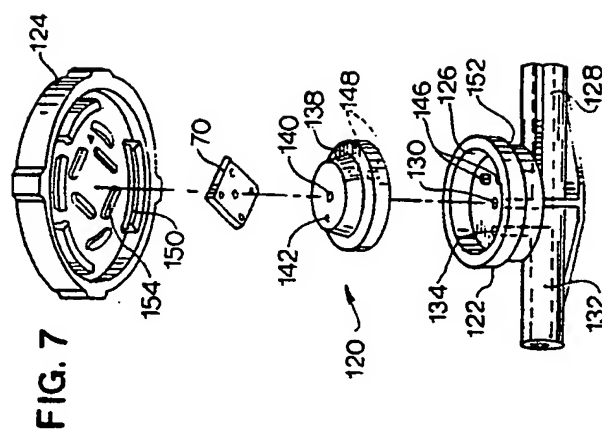


FIG. 6





# INTERNATIONAL SEARCH REPORT

International Application No PCT/US90/02052

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>3</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC (5) : A61M 5/00		
U.S. CL : 604/132		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>4</sup>		
Classification System	Classification Symbols	
U.S.	604/131,132,246,151,153; 120/DIG 12	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>5</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <sup>14</sup>		
Category <sup>6</sup>	Citation of Document, <sup>16</sup> with indication, where appropriate, of the relevant passages <sup>15</sup>	Relevant to Claim No. <sup>17</sup>
Y,P	US,A 4,898,585 (BORSANYI ET AL) 06 February 1990, See entire document.	1-16
A	US,A 4,209,014 (SEFTON) 24 June 1980 See Column 2, Lines 34-64.	1-16
<u>Y</u> A	US,A 4,601,707 (ABISSER ET AL) 22 July 1986 See entire document.	<u>1,2,4,5</u> 3,6-16
A	US,A 4,699,615 (FISCHELL ET AL) 13 October 1977. See Column 3, Lines 44-60.	1-16
A	US,A 4,548,599 (URQUHART ET AL) 22 October 1985. See entire document.	1
A	PCT 87/00758 (WINCHELL ET AL) 12 February 1987. See entire document.	1-2,4,7, 9-16
(Con't)		
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><sup>18</sup> * Special categories of cited documents: <sup>13</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"Δ" document member of the same patent family</p> </div> </div>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search <sup>2</sup>	Date of Mailing of this International Search Report <sup>2</sup>	
23 June 1990	07 AUG 1990	
International Searching Authority <sup>1</sup>	Signature of Authorized Officer <sup>20</sup>	
ISA/US	Kathleen A. Daley	

## FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A

PCT 86/03978 (WINCHELL ET AL)  
See entire document.

1,3,10-15

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE<sup>1</sup>

This International search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers \_\_\_\_\_, because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim numbers \_\_\_\_\_, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out<sup>1</sup>, specifically:
3. ☐ Claim numbers \_\_\_\_\_, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING<sup>2</sup>

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

## Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.